



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Bernd RIEDL et al.

Confirmation No.: 6634

Serial No.: 10/042,203

Examiner: Rita J. Desai

Filed: January 11, 2002

Group Art Unit: 1625

Title: **Ω -CARBOXYARYL SUBSTITUTED DIPHENYL UREAS AS RAF KINASE INHIBITORS**

Declaration under 37 CFR § 131

MAIL STOP NON FINAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, the undersigned, being duly warned declare that:

We are co-inventors named in the above-identified application.

We are co-inventors of subject matter disclosed in US PROVISIONAL APPLICATION NUMBER 60/115,877, filed on January 13, 1999.

We have reviewed claims 68 and 122-137 now pending in the above application and we believe we are the co-inventors of the subject matter of claims 134-136 therein.

As evidenced by compound numbers 42 and 43 within the tables of US PROVISIONAL APPLICATION NUMBER 60/115,877, filed on January 13, 1999, we invented these compounds at least as early as January 13, 1999.

Any description of the subject matter of claims 134-136 within the following applications, assigned to the same assignee as the present invention, is a description of our invention.

US 60/115,878, FILED 01/13/1999;
US 60/115,877, FILED 01/13/1999;
US 9/257,265, FILED 02/25/1999;
US 09/257,266, FILED 02/25/1999;
US 09/425,228, FILED 10/22/1999;
US 09/425,229, FILED 10/22/1999;

PCT/US 00/00768, FILED 01/13/2000;
PCT/US 00/00648, FILED 01/13/2000;

US 09/722,418, FILED 11/28/2000;

US 09/758,266, FILED 01/12/2001;
US 09/758,548, FILED 01/12/2001;
US 09/758,549, FILED 01/12/2001;
US 09/773,659, FILED 02/02/2001;
US 09/773,675, FILED 02/02/2001;
US 09/773,672, FILED 02/02/2001;
US 09/773,658, FILED 02/02/2001;
US 09/773,604, FILED 02/02/2001;
US 09/777,920, FILED 02/07/2001;
US 09/889,227, FILED 07/12/2001;
US 09/907,970, FILED 07/19/2001;
US 09/948,915, FILED 09/10/2001;
US 09/993,647, FILED 11/27/2001;
US 60/334,609, FILED 12/03/2001;

US 10/042,226, FILED 01/11/2002;
US 10/071,248, FILED 02/11/2002;
US 60/354,950, FILED 02/11/2002;
US 60/354,937, FILED 02/11/2002;
US 10/086,417, FILED 03/04/2002
US 10/308,187, FILED 12/03/2002;

PCT/US 02/03361, FILED 02/07/2002;
PCT/US 02/38439, FILED 12/03/2002;

US 10/361,358, FILED 02/11/2003;
US 10/361,859, FILED 02/11/2003;
US 60/471,735, FILED 05/20/2003;
US 60/489,102, FILED 07/23/2003;
US 10/659,639, FILED 09/11/2003
US 60/520,399, FILED 11/17/2003;

PCT/US 03/04103, FILED 02/11/2003;
PCT/US 03/04109, FILED 02/11/2003;

US 60/536,734, FILED 01/16/2004;
US 60/540,326, FILED 02/02/2004;
US 60/556,062, FILED 03/25/2004;
US 10/848,567, FILED 05/19/2004;
US 10/895,985, FILED 07/22/2004;

US 60/604,752, FILED 08/27/2004;
US 60/604,753, FILED 08/27/2004;

PCT/US 04/15655, FILED 05/19/2004;
PCT/US 04/15653, FILED 05/19/2004;
PCT/US 04/23500, FILED 07/22/2004;

US 60/658,827, FILED 03/07/2005 AND
US 60/731,277, FILED 10/31/2005.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Bernd Riedl, Date

Jacques Dumas, Date

Uday Khire, Date

Timothy B. Lowinger Date

William J. Scott Date

Roger A. Smith Date

Jill E. Wood Date

Reina Natero Date

(C), will be subject to a restriction requirement. Applicants will be required to select one combination for examination. If the selected combination contains ten or fewer sequences, all of the sequences of the combination will be searched. If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth above for example (B). More specifically, the combination will be searched until one nucleotide sequence is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed.

In applications containing all three claims set forth in examples (A)-(C), the Office will require restriction of the application to ten sequences for initial examination purposes. Based upon the finding of allowable sequences, claims limited to the allowable sequences as in example (A), all combinations, such as in examples (B) and (C), containing the allowable sequences and any patentably indistinct sequences will be rejoined and allowed.

****>Nonelected claims< requiring any allowable >nucleotide< sequence(s) >should be considered for rejoinder. See MPEP § 821.04<. ****

804 Definition of Double Patenting [R-3]

35 U.S.C. 101. *Inventions Patentable.*

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. 121. *Divisional Applications.*

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Director may dispense with signing and execution by the inventor.

The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The public policy behind this doctrine is that:

The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent.

In re Zickendraht, 319 F.2d 225, 232, 138 USPQ 22, 27 (CCPA 1963) (Rich, J., concurring). Double patenting results when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent or patents. *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982).

Before consideration can be given to the issue of double patenting, ** two or more patents or applications >must have at least one common inventor and/or be either commonly assigned/owned or non-commonly assigned/owned but subject to a joint research agreement as set forth in 35 U.S.C. 103(c)(2) and (3) pursuant to the CREATE Act (Pub. L. 108-453, 118 Stat. 3596 (2004)). Congress recognized that the amendment to 35 U.S.C. 103(c) would result in situations in which there would be double patenting rejections between applications not owned by the same party (see H.R. Rep. No. 108-425, at 5-6 (2003)). For purposes of a double patenting analysis, the application or patent and the subject matter disqualified under 35 U.S.C. 103(c) as amended by the CREATE Act will be treated as if commonly owned. See also MPEP § 804.03.< Since the doctrine of double patenting seeks to avoid unjustly extending patent rights at the expense of the public, the focus of any double patenting analysis necessarily is on the claims in the multiple patents or patent applications involved in the analysis.

There are generally two types of double patenting rejections. One is the "same invention" type double patenting rejection based on 35 U.S.C. 101 which states in the singular that an inventor "may obtain a patent." The second is the "nonstatutory-type" double patenting rejection based on a judicially created

I. INSTANCES WHERE DOUBLE PATENTING ISSUE CAN BE RAISED

A double patenting issue may arise between two or more pending applications, >or< between one or more pending applications and a patent**. A double patenting issue may likewise arise in a reexamination proceeding between the patent claims being reexamined and the claims of one or more applications and/or patents. Double patenting does not relate to international applications which have not yet entered the national stage in the United States.

A. *Between Issued Patent and One or More Applications*

Double patenting may exist between an issued patent and an application filed by the same inventive entity, or by *>a different< inventive entity having a common inventor **, and/or by **>a common assignee/owner. Double patenting may also exist where the inventions claimed in a patent and an application were made as a result of activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 103(c)(2) and (3).< Since the inventor/patent owner has already secured the issuance of a first patent, the examiner must determine whether the grant of a second patent would give rise to an unjustified extension of the rights granted in the first patent.

B. *Between Copending Applications—Provisional Rejections*

Occasionally, the examiner becomes aware of two copending applications >that were< filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee >, or that claim an invention resulting from activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 103(c)(2) and (3),< that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications (35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to

make a “provisional” rejection on the ground of double patenting. *In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue.

The “provisional” double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that “provisional” double patenting rejection is the only rejection remaining in >at least< one of the applications. **

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1. Nonstatutory Double Patenting Rejections

If a “provisional” nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

If “provisional” ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Where there are three applications containing claims that conflict such that an ODP rejection is made in each application based upon the other two, it is not sufficient to file a terminal disclaimer in only one of the applications addressing the other two applications. Rather, an appropriate terminal disclaimer must be filed in at least two of the applications to link all three together. This is because a terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the application in which the terminal disclaimer is filed; it is not effective to link the other two applications to each other.

2. Statutory Double Patenting Rejections (35 U.S.C. 101)

A terminal disclaimer cannot be filed to obviate a statutory double patenting rejection.

If a “provisional” statutory double patenting rejection is the only rejection remaining in one of the applications (but not both), the examiner should withdraw the rejection in that application and permit that application to issue as a patent, thereby converting the “provisional” double patenting rejection in the other application into a double patenting rejection when the application issues as a patent.

If a “provisional” statutory double patenting rejection is the only rejection remaining in both applications, the examiner should withdraw that rejection in the application with the earlier filing date and permit that application to issue as a patent. If both applications were filed on the same day, the applicant should be given an opportunity to elect which of the two should be allowed. In either situation, the examiner should maintain the double patenting rejection in the other application as a “provisional” double patenting rejection, which will be converted into a double patenting rejection when one application issues as a patent.

C. Between One or More Applications and a Published Application - Provisional Rejections

Double patenting may exist *where a published patent application and an application are filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee. Double patenting may also exist where a published application and an application claim inventions resulting from activities undertaken

within the scope of a joint research agreement as defined in 35 U.S.C. 103(c)(2) and (3). Since the published application has not yet issued as a patent, the examiner is permitted to make a “provisional” rejection on the ground of double patenting when the published application has not been abandoned and claims pending therein conflict with claims of the application being examined. See the discussion regarding “provisional” double patenting *rejections in subsection B. above.

D. Reexamination Proceedings

A double patenting issue may raise a substantial new question of patentability of a claim of a patent, and thus be addressed in a reexamination proceeding. *In re Lonardo*, 119 F.3d 960, 966, 43 USPQ2d 1262, 1266 (Fed. Cir. 1997) (In giving the *Director authority under 35 U.S.C. 303(a) in determining the presence of a substantial new question of patentability, “Congress intended that the phrases ‘patents and publications’ and ‘other patents or publications’ in section 303(a) not be limited to *prior art* patents or printed publications.” (emphasis added)). Accordingly, if the issue of double patenting was not addressed during original prosecution, it may be considered during reexamination.

>Double patenting may exist where a reference patent or application and the patent under reexamination are filed by inventive entities that have at least one inventor in common and/or are filed by a common owner/assignee. Where the patent under reexamination was granted on or after December 10, 2004, double patenting may also exist where the inventions claimed in the reference and reexamination proceeding resulted from activities undertaken within the scope of a joint research agreement pursuant to 35 U.S.C. 103(c)(2) and (3), and if evidence of the joint research agreement has been made of record in the patent being reexamined or in the reexamination proceeding. A double patenting rejection may NOT be made on this basis if the patent under reexamination issued before December 10, 2004. See MPEP § 804.04. The prior art exclusion under 35 U.S.C. 103(c) cannot be used to overcome an obvious double patenting rejection. See MPEP § 706.02(I) for more information on 35 U.S.C. 103(c). See MPEP § 2258 for more information on making double patenting rejections in reexamination proceedings.